

SUPPORT FOR THE AMENDMENTS

Claim 6 has been canceled.

No new matter has been added by the present amendment.

REMARKS

Claims 1-5 and 7-9 are pending in the present application.

The rejection of Claims 5 and 6 under 35 U.S.C. §102(b) over Iwao et al (JP 2003-095942) is respectfully traversed.

At the outset, Applicants note that Claim 6 has been canceled. Applicants make no statement with respect to the propriety of the rejection of Claim 6 and in no way acquiesce to the same. The cancellation of Claim 6 is solely for the purpose of expediting examination of Claim 5.

In the Office Action, the Examiner cites Iwao et al as allegedly disclosing “a method to reinforce and increase activation of the muscular system, improvement in athletic ability (improving endurance), fatigue mitigation (ameliorating fatigue) by administering catechin gallate (a catechin) (see paragraphs [0011]-[0013]).” Applicants disagree with the Examiner’s allegations.

Iwao et al disclose:

Glucose intake activation effect in muscle tissue,

GLUT4 translocation effect in muscle tissue (without data),

Glucose intake inhibition effect in adipose tissue, and

GLUT4 translocation inhibition effect in adipose cells.

Iwao et al further speculates that as a result of activation of glucose intake in muscle tissue, the amount of muscle cells are increased. As such, the active ingredient, which increases glucose intake in muscle tissue, has resulting effects such as muscle tissue activation, reduction in physical exhaustion, increased ability for exercise, buildup of muscle

tissue, and improving physical condition. However, Iwao et al does not directly disclose an endurance improving effect.

With respect to the foregoing, although Iwao et al disclose activation of GLUT4 translocation and glucose intake activation results in an increased ability for exercise, the word “ability for exercise” has several meanings which are not synonymous with or the same as improved endurance. The “ability for exercise” relates to, for example, agility, muscle force, instantaneous force.

Applicants submit herewith the following three references that evidence the activation of GLUT4 translocation and glucose intake activation do not have any relation with endurance improving effect:

- 1) Gaster et al. Eur J Physiol (2001) 443:196-201
- 2) Bao et al. Metabolism, Vol. 48, No. 11, 1987, 1349-1357
- 3) Tsao et al. The FSAB Journal (2001) Vol 15 April 958-968

In view of these references, Applicants submit that:

(A) Activation of GLUT4 translocation does not set off endurance improving effect.

Gaster et al disclose that GLUT4 density in slow-twitch fibers and fast-twitch fibers was identical in athletes compared to control subject (see page 198, right column, lines 3-7). Thus Gaster et al show that there is no relation between GLUT4 level and improved endurance.

(B) Overexpression of GLUT4 contributes to increasing of lactate concentration in serum.

Bao et al discloses that overexpression of GLUT4 contributes to increasing of blood lactate concentration (see page 1350, right column, lines 12-24 and Table 1). Lactate is a

well known causative substance for muscle fatigue. Clearly an increased concentration of lactate would not lead to an increase in endurance.

(C) Overexpression of GLUT4 changes carbohydrate and lipid utilization rate.

Bao et al discloses that GLUT4 TG mice metabolize more carbohydrate than WT mice and the former metabolize less lipid than latter (see page 1351, right column, line 12 to page 1352, left column, line 4 and Fig. 4). In general, the use of lipids as energy source is suitable for long time exercise (endurance exercise). Again, Bao et al show that improved endurance would not be apparent from overexpression of GLUT4.

Applicants further submit that Tsao et al disclose overexpression of GLUT4 does not set off increasing of muscle tissue (see table 1). As shown in Table 1, the amount of muscle tissue is decreased in some muscle tissues. Tsao et al also speculate that overexpression of GLUT4 contributes to an increase in lactate concentration in blood (see page 965, right column, lines 33-40). Applicants note that Tsao et al disclose in Figure 6 and 7 that certain MLC-GLUT4 mice run more distance than wildtype mice. However, this *voluntary* exercise test is a measure of will not of endurance and should not be confused with improved endurance.

In view of the foregoing, Applicants submit that there is no relation between activation of GLUT4 translocation and endurance improving effect. Indeed, activation of GLUT4 translocation has negative effects on endurance (lactate level and metabolize carbohydrate). Thus, there is no disclosure or suggestion in Iwao et al to administer catechins to improve endurance as the Examiner alleges. As such, Applicants submit that the claimed invention is not anticipated by Iwao et al.

Applicants request withdrawal of this ground of rejection.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)